On the day prior to the colonoscopy, instruct patients to:

- drink 2.5 liters of PEG-3350 and Electrolytes for Oral Solution, especially if it is administered via nasogastric tube.
- limit oral intake of food and fluids 12 hours before the scheduled time of colonoscopy.

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to confirm the diagnosis. Bowel perforation should be treated surgically. Bowel perforation may result in peritonitis that may require emergency surgery. There have been reports of more serious cases of ischemic colitis requiring hospitalization. Concur.

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

In patients at increased risk of ischemic colitis, consider use of prophylactic intravenous fluid boluses. The decision to use prophylactic intravenous fluid boluses should be individualized based on the risk of ischemic colitis.

Avoid use of stimulant laxatives (e.g., bisacodyl, senna). Avoid use of any osmotic medication that will result in fluid shifts that may precipitate electrolyte disturbances.

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to confirm the diagnosis. Bowel perforation should be treated surgically. Bowel perforation may result in peritonitis that may require emergency surgery. There have been reports of more serious cases of ischemic colitis requiring hospitalization. Concur.

6. ADVERSE REACTIONS

The following adverse reactions have been identified during postapproval use of PEG-3350 and Electrolytes for Oral Solution. These reactions are reported voluntarily from a population of patients using PEG-3350 and Electrolytes for Oral Solution. Because these reactions are reported voluntarily from a population of patients, it is not always possible to reliably estimate how often they occur or if a causal relationship exists to the medication.

6.1 Gastrointestinal

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain
- Abdominal distention
- Constipation
- Flatulence
- Bloating
- Gastritis
- Peptic ulcer disease
- Colitis

6.2 Central Nervous System

- Headache
- Dizziness
- Numbness
- Weakness
- Paralysis
- Seizure

6.3 Respiratory

- Rhinorrhea
- Cough

6.4 Miscellaneous

- Anaphylactic reaction
- Shock
- Allergic reaction

7. DRUG INTERACTIONS

There are no known drug interactions with PEG-3350 and Electrolytes for Oral Solution.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

PEG-3350 and Electrolytes for Oral Solution is not a drug that is known to cause fetal harm when administered to a pregnant woman. PEG-3350 and Electrolytes for Oral Solution should be given to a pregnant woman only if clearly needed.

8.2 Nursing Mothers

PEG-3350 and Electrolytes for Oral Solution should be given to a nursing woman only if clearly needed.

8.3 Children

PEG-3350 and Electrolytes for Oral Solution is indicated for bowel cleansing prior to colonoscopy and barium enema X-ray examination in adults.

8.4 Geriatric Use

Safety and effectiveness of PEG-3350 and Electrolytes for Oral Solution in pediatric patients have not been established.

8.5 Pediatric Use

PEG-3350 and Electrolytes for Oral Solution is not a drug that is known to cause fetal harm when administered to a pregnant woman. PEG-3350 and Electrolytes for Oral Solution should be given to a pregnant woman only if clearly needed.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The pharmacologic effects of polyethylene glycol are related to its osmotic colonic lavage activity. The osmotic activity of polyethylene glycol results in an osmotic gradient between the intraluminal and extraluminal compartments of the colon. This gradient induces fluid and electrolyte shifts from the intravascular compartment to the lumen of the colon. The fluid and electrolyte shifts cause a bulk movement of fluid from the intraluminal space of the colon to the intravascular space, resulting in the net effect of cleansing the colon of contents.

12.2 Pharmacodynamics

The chemical name is NaCl. The average Molecular Weight: 58.44. The structural formula is: 

\[ \text{H}_2\text{O} \quad \text{Na}^+ \quad \text{O}^- \quad \text{S} \]

Full prescribing information is available at the following URL: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020535s024lbl.pdf

9 CLINICAL PHARMACOLOGY

The primary mode of action is thought to be through the osmotic effect of polyethylene glycol 3350 that causes fluid and electrolyte shifts from the intravascular compartment to the lumen of the colon. The osmotic activity of polyethylene glycol results in an osmotic gradient between the intraluminal and extraluminal compartments of the colon. This gradient induces fluid and electrolyte shifts from the intravascular compartment to the lumen of the colon. The fluid and electrolyte shifts cause a bulk movement of fluid from the intravascular space of the colon to the intravascular space, resulting in the net effect of cleansing the colon of contents.
These changes can cause:
- Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) and changes in body fluid levels (electrolytes)
- Serious side effects, including:
  - Severe dehydration
  - Electrolyte imbalance
  - Abnormal heart rhythm

PEG-3350 and Electrolytes for Oral Solution and other osmotic bowel preparations can cause serious side effects, including:
- Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.
- These changes can cause:
  - Abnormal heartbeats that can cause death
  - Seizures
  - Kidney problems

Your chance of having fluid loss and changes in body salts with PEG-3350 and Electrolytes for Oral Solution is higher if you:
- Have heart problems
- Have kidney problems
- Take oral sedatives or non-steroidal anti-inflammatory drugs (NSAIDs)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking PEG-3350 and Electrolytes for Oral Solution:
- Vomiting or diarrhea that prevents you from keeping down the solution
- Nausea
- Urinating less than normal

See Section “What are the possible side effects of PEG-3350 and Electrolytes for Oral Solution” to learn about other possible side effects of PEG-3350 and Electrolytes for Oral Solution.

What is PEG-3350 and Electrolytes for Oral Solution?
PEG-3350 and Electrolytes for Oral Solution is a prescription medicine used to help clean the inside of your colon before a colonoscopy. It is also used to lower the amount of fluids in your stool when you have problems with food and fluid emptying from your stomach (gastric retention) or an opening in the wall of your stomach or intestine (bowel perforation) or a blockage in your bowel (obstruction).

What should I tell my healthcare provider before taking PEG-3350 and Electrolytes for Oral Solution?
Before you take PEG-3350 and Electrolytes for Oral Solution, tell your healthcare provider if you:
- Have heart problems
- Have kidney problems
- Take oral sedatives or non-steroidal anti-inflammatory drugs (NSAIDs)
- Are pregnant
- Are breastfeeding or plan to breastfeed
- Have kidney problems
- Have problems with swallowing or gastric reflux
- Have trouble drinking clear liquid
- Are allergic to polyethylene glycol 3350, sodium sulfate, sodium bicarbonate, or sodium chloride
- Have had an allergic reaction to PEG-3350 and Electrolytes for Oral Solution
- Have had an allergic reaction to other bowel preparations

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. PEG-3350 and Electrolytes for Oral Solution may affect how other medicines work. Tell your healthcare provider if you take any of the medicines listed above.

How should I store PEG-3350 and Electrolytes for Oral Solution?
Store in sealed container at 59° to 86°F (15°C to 30°C). When reconstituted, keep solution refrigerated at 36° to 46°F (2° to 8°C) for up to 24 hours.

Do not eat or drink anything colored red or purple.

PEG-3350 and Electrolytes for Oral Solution can cause serious side effects, including:
- Severe dehydration
- Electrolyte imbalance
- Abnormal heart rhythm

The most common side effects of PEG-3350 and Electrolytes for Oral Solution include:
- Nausea
- Stomach (abdominal) fullness
- Rectal bleeding
- Headache
- Vomiting that prevents you from keeping down the solution

What are the ingredients in PEG-3350 and Electrolytes for Oral Solution?
PEG-3350 and Electrolytes for Oral Solution contains:
- Polyethylene glycol 3350 236 g
- Sodium sulfate (anhydrous) 22.74 g
- Sodium bicarbonate 6.74 g
- Sodium chloride 5.86 g
- Potassium carbonate 20 mmol/L

How should I take PEG-3350 and Electrolytes for Oral Solution?
Take PEG-3350 and Electrolytes for Oral Solution exactly as your healthcare provider tells you to take it. You can take PEG-3350 and Electrolytes for Oral Solution by drinking:
- Clear soda (Do not use any dairy or non-dairy creamer)
- Coffee (Do not use any dairy or non-dairy creamer)
- Water
- Popsicles without pieces of fruit or fruit pulp

Do not eat or drink anything colored red or purple.